107TH CONGRESS 2D SESSION

S. 2736

To amend title XVIII of the Social Security Act to provide medicare beneficiaries with a drug discount card that ensures access to affordable outpatient prescription drugs.

IN THE SENATE OF THE UNITED STATES

July 16, 2002

Mr. Hagel (for himself, Mr. Ensign, Mr. Lugar, Mr. Gramm, and Mr. Inhofe) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

- To amend title XVIII of the Social Security Act to provide medicare beneficiaries with a drug discount card that ensures access to affordable outpatient prescription drugs.
 - 1 Be it enacted by the Senate and House of Representa-
 - 2 tives of the United States of America in Congress assembled,
 - 3 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.
 - 4 (a) Short Title.—This Act may be cited as the
 - 5 "Medicare Rx Drug Discount and Security Act of 2002".
- 6 (b) Table of Contents.—The table of contents of
- 7 this Act is as follows:
 - Sec. 1. Short title; table of contents.

- Sec. 2. Voluntary Medicare Outpatient Prescription Drug Discount and Security Program.
 - "Part D—Voluntary Medicare Outpatient Prescription Drug Discount and Security Program
 - "Sec. 1860. Definitions.
 - "Sec. 1860A. Establishment of program.
 - "Sec. 1860B. Enrollment.
 - "Sec. 1860C. Providing enrollment and coverage information to beneficiaries.
 - "Sec. 1860D. Enrollee protections.
 - "Sec. 1860E. Annual enrollment fee.
 - "Sec. 1860F. Benefits under the program.
 - "Sec. 1860G. Selection of entities to provide prescription drug coverage.
 - "Sec. 1860H. Payments to eligible entities for administering the catastrophic benefit.
 - "Sec. 1860I. Determination of income levels.
 - "Sec. 1860J. Appropriations.
 - "Sec. 1860K. Medicare Competition and Prescription Drug Advisory Board.".
- Sec. 3. Administration of Voluntary Medicare Outpatient Prescription Drug Discount and Security Program.
- Sec. 4. Exclusion of part D costs from determination of part B monthly premium.
- Sec. 5. Medigap revisions.

1 SEC. 2. VOLUNTARY MEDICARE OUTPATIENT PRESCRIP-

- 2 TION DRUG DISCOUNT AND SECURITY PRO-
- GRAM.
- 4 (a) Establishment of Program.—Title XVIII of
- 5 the Social Security Act (42 U.S.C. 1395 et seq.) is
- 6 amended—
- 7 (1) by redesignating part D as part E; and
- 8 (2) by inserting after part C the following new
- 9 part:

1	"Part D—Voluntary Medicare Outpatient Pre-
2	SCRIPTION DRUG DISCOUNT AND SECURITY PRO-
3	GRAM
4	"DEFINITIONS
5	"Sec. 1860. In this part:
6	"(1) Covered outpatient drug.—
7	"(A) In general.—Except as provided in
8	this paragraph, the term 'covered outpatient
9	drug' means—
10	"(i) a drug that may be dispensed
11	only upon a prescription and that is de-
12	scribed in subparagraph (A)(i) or (A)(ii) of
13	section $1927(k)(2)$; or
14	"(ii) a biological product described in
15	clauses (i) through (iii) of subparagraph
16	(B) of such section or insulin described in
17	subparagraph (C) of such section,
18	and such term includes a vaccine licensed under
19	section 351 of the Public Health Service Act
20	and any use of a covered outpatient drug for a
21	medically accepted indication (as defined in sec-
22	tion $1927(k)(6)$).
23	"(B) Exclusions.—
24	"(i) In general.—Such term does
25	not include drugs or classes of drugs, or

their medical uses, which may be excluded 1 2 coverage or otherwise from restricted under section 1927(d)(2), other than sub-3 paragraph (E) thereof (relating to smoking cessation agents), under or section 6 1927(d)(3). 7 "(ii) Avoidance of duplicate cov-

"(n) Avoidance of duplicate coverage.—A drug prescribed for an individual that would otherwise be a covered outpatient drug under this part shall not be so considered if payment for such drug is available under part A or B for an individual entitled to benefits under part A and enrolled under part B.

"(C) APPLICATION OF FORMULARY RE-STRICTIONS.—A drug prescribed for an individual that would otherwise be a covered outpatient drug under this part shall not be so considered under a plan if the plan excludes the drug under a formulary and such exclusion is not successfully appealed under section 1860D(a)(4)(B).

"(D) APPLICATION OF GENERAL EXCLUSION PROVISIONS.—A prescription drug discount card plan or Medicare+Choice plan may

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1	exclude from qualified prescription drug cov-
2	erage any covered outpatient drug—
3	"(i) for which payment would not be
4	made if section 1862(a) applied to part D
5	or
6	"(ii) which are not prescribed in ac-
7	cordance with the plan or this part.
8	Such exclusions are determinations subject to
9	reconsideration and appeal pursuant to section
10	1860D(a)(4).
11	"(2) Eligible beneficiary.—The term 'eligi-
12	ble beneficiary' means an individual who is—
13	"(A) eligible for benefits under part A or
14	enrolled under part B; and
15	"(B) not eligible for prescription drug cov-
16	erage under a State plan under the medicaid
17	program under title XIX.
18	"(3) Eligible entity.—The term 'eligible en-
19	tity' means any—
20	"(A) pharmaceutical benefit management
21	company;
22	"(B) wholesale pharmacy delivery system;
23	"(C) retail pharmacy delivery system;

1	"(D) insurer (including any issuer of a
2	medicare supplemental policy under section
3	1882);
4	"(E) Medicare+Choice organization;
5	"(F) State (in conjunction with a pharma-
6	ceutical benefit management company);
7	"(G) employer-sponsored plan;
8	"(H) other entity that the Secretary deter-
9	mines to be appropriate to provide benefits
10	under this part; or
11	"(I) combination of the entities described
12	in subparagraphs (A) through (H).
13	"(4) Out-of-pocket expenses.—The term
14	'out-of-pocket expenses' means only those expenses
15	for covered outpatient drugs that are incurred by the
16	eligible beneficiary using a card approved by the
17	Secretary under this part that are paid by that bene-
18	ficiary and for which the beneficiary is not reim-
19	bursed (through insurance or otherwise) by another
20	person.
21	"(5) Poverty line.—The term 'poverty line'
22	means the income official poverty line (as defined by
23	the Office of Management and Budget, and revised
24	annually in accordance with section 673(2) of the

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1	Omnibus Budget Reconciliation Act of 1981) appli-
2	cable to a family of the size involved.
3	"(6) Secretary.—The term 'Secretary' means
4	the Secretary of Health and Human Services, acting
5	through the Administrator of the Centers for Medi-
6	care & Medicaid Services.
7	"ESTABLISHMENT OF PROGRAM
8	"Sec. 1860A. (a) Provision of Benefit.—The
9	Secretary shall establish a Medicare Outpatient Prescrip-
10	tion Drug Discount and Security Program under which
11	the Secretary endorses prescription drug card plans of-
12	fered by eligible entities in which eligible beneficiaries may
13	voluntarily enroll and receive benefits under this part.
14	"(b) Endorsement of Prescription Drug Dis-
15	COUNT CARD PLANS.—
16	"(1) IN GENERAL.—The Secretary shall en-
17	dorse a prescription drug card plan offered by an eli-
18	gible entity with a contract under this part if the eli-
19	gible entity meets the requirements of this part with
20	respect to that plan.
21	"(2) NATIONAL PLANS.—In addition to other
22	types of plans, the Secretary may endorse national
23	prescription drug plans under paragraph (1).
24	"(c) Voluntary Nature of Program.—Nothing
25	in this part shall be construed as requiring an eligible ben-

26 eficiary to enroll in the program under this part.

1	"(d) Financing.—The costs of providing benefits
2	under this part shall be payable from the Federal Supple-
3	mentary Medical Insurance Trust Fund established under
4	section 1841.
5	"ENROLLMENT
6	"Sec. 1860B. (a) Enrollment Under Part D.—
7	"(1) Establishment of process.—
8	"(A) IN GENERAL.—The Secretary shall
9	establish a process through which an eligible
10	beneficiary (including an eligible beneficiary en-
11	rolled in a Medicare+Choice plan offered by a
12	Medicare+Choice organization) may make an
13	election to enroll under this part. Except as
14	otherwise provided in this subsection, such
15	process shall be similar to the process for en-
16	rollment under part B under section 1837.
17	"(B) Requirement of enrollment.—
18	An eligible beneficiary must enroll under this
19	part in order to be eligible to receive the bene-
20	fits under this part.
21	"(2) Enrollment periods.—
22	"(A) IN GENERAL.—Except as provided in
23	this paragraph, an eligible beneficiary may not
24	enroll in the program under this part during
25	any period after the beneficiary's initial enroll-

1	ment period under part B (as determined under
2	section 1837).
3	"(B) Special enrollment period.—In
4	the case of eligible beneficiaries that have re-
5	cently lost eligibility for prescription drug cov-
6	erage under a State plan under the medicaid
7	program under title XIX, the Secretary shall
8	establish a special enrollment period in which
9	such beneficiaries may enroll under this part.
10	"(C) Open enrollment period in 2003
11	FOR CURRENT BENEFICIARIES.—The Secretary
12	shall establish a period, which shall begin on
13	the date on which the Secretary first begins to
14	accept elections for enrollment under this part,
15	during which any eligible beneficiary may—
16	"(i) enroll under this part; or
17	"(ii) enroll or reenroll under this part
18	after having previously declined or termi-
19	nated such enrollment.
20	"(3) Period of Coverage.—
21	"(A) IN GENERAL.—Except as provided in
22	subparagraph (B) and subject to subparagraph
23	(C), an eligible beneficiary's coverage under the
24	program under this part shall be effective for
25	the period provided under section 1838, as if

1	that section applied to the program under this
2	part.
3	"(B) Enrollment during open and
4	SPECIAL ENROLLMENT.—Subject to subpara-
5	graph (C), an eligible beneficiary who enrolls
6	under the program under this part under sub-
7	paragraph (B) or (C) of paragraph (2) shall be
8	entitled to the benefits under this part begin-
9	ning on the first day of the month following the
10	month in which such enrollment occurs.
11	"(4) Part d coverage terminated by ter-
12	MINATION OF COVERAGE UNDER PARTS A AND B OR
13	ELIGIBILITY FOR MEDICAL ASSISTANCE.—
14	"(A) In General.—In addition to the
15	causes of termination specified in section 1838,
16	the Secretary shall terminate an individual's
17	coverage under this part if the individual is—
18	"(i) no longer enrolled in part A or B;
19	or
20	"(ii) eligible for prescription drug cov-
21	erage under a State plan under the med-
22	icaid program under title XIX.
23	"(B) Effective date.—The termination
24	described in subparagraph (A) shall be effective
25	on the effective date of—

1	"(i) the termination of coverage under
2	part A or (if later) under part B; or
3	"(ii) the coverage under title XIX.
4	"(b) Enrollment With Eligible Entity.—
5	"(1) Process.—The Secretary shall establish a
6	process through which an eligible beneficiary who is
7	enrolled under this part shall make an annual elec-
8	tion to enroll in a prescription drug card plan of-
9	fered by an eligible entity that has been awarded a
10	contract under this part and serves the geographic
11	area in which the beneficiary resides.
12	"(2) Election periods.—
13	"(A) In general.—Except as provided in
14	this paragraph, the election periods under this
15	subsection shall be the same as the coverage
16	election periods under the Medicare+Choice
17	program under section 1851(e), including—
18	"(i) annual coordinated election peri-
19	ods; and
20	"(ii) special election periods.
21	In applying the last sentence of section
22	1851(e)(4) (relating to discontinuance of a
23	Medicare+Choice election during the first year
24	of eligibility) under this subparagraph, in the
25	case of an election described in such section in

which the individual had elected or is provided qualified prescription drug coverage at the time of such first enrollment, the individual shall be permitted to enroll in a prescription drug card plan under this part at the time of the election of coverage under the original fee-for-service plan.

"(B) Initial election periods.—

"(i) Individuals currently covered.—In the case of an individual who is entitled to benefits under part A or enrolled under part B as of November 1, 2003, there shall be an initial election period of 6 months beginning on that date.

"(ii) Individual covered in future.—In the case of an individual who is first entitled to benefits under part A or enrolled under part B after such date, there shall be an initial election period which is the same as the initial enrollment period under section 1837(d).

"(C) Additional special election periods—

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1	"(i) in cases of individuals who have
2	and involuntarily lose prescription drug
3	coverage described in paragraph (3);
4	"(ii) in cases described in section
5	1837(h) (relating to errors in enrollment),
6	in the same manner as such section applies
7	to part B; and
8	"(iii) in the case of an individual who
9	meets such exceptional conditions (includ-
10	ing conditions provided under section
11	1851(e)(4)(D)) as the Secretary may pro-
12	vide.
13	"(D) Enrollment with one plan
14	ONLY.—The rules established under subpara-
15	graph (B) shall ensure that an eligible bene-
16	ficiary may only enroll in 1 prescription drug
17	card plan offered by an eligible entity for a
18	year.
19	"(3) Medicare+choice enrollees.—An eli-
20	gible beneficiary who is enrolled under this part and
21	enrolled in a Medicare+Choice plan offered by a
22	Medicare+Choice organization must enroll in a pre-
23	scription drug discount card plan offered by an eligi-
24	ble entity in order to receive benefits under this
25	part. The beneficiary may elect to receive such bene-

fits through the Medicare+Choice organization in which the beneficiary is enrolled if the organization has been awarded a contract under this part.

"(4) Continuous prescription drug coverage.—An individual is considered for purposes of this part to be maintaining continuous prescription drug coverage on and after the date the individual first qualifies to elect prescription drug coverage under this part if the individual establishes that as of such date the individual is covered under any of the following prescription drug coverage and before the date that is the last day of the 63-day period that begins on the date of termination of the particular prescription drug coverage involved (regardless of whether the individual subsequently obtains any of the following prescription drug coverage):

- "(A) COVERAGE UNDER PRESCRIPTION
 DRUG CARD PLAN OR MEDICARE+CHOICE
 PLAN.—Prescription drug coverage under a prescription drug card plan under this part or
 under a Medicare+Choice plan.
- "(B) Medicaid prescription drug coverage under a medicaid plan under title XIX, including through the Program of All-inclusive Care for

the Elderly (PACE) under section 1934, through a social health maintenance organization (referred to in section 4104(c) of the Balanced Budget Act of 1997), or through a Medicare+Choice project that demonstrates the application of capitation payment rates for frail elderly medicare beneficiaries through the use of a interdisciplinary team and through the provision of primary care services to such beneficiaries by means of such a team at the nursing facility involved.

"(C) Prescription drug coverage under a group health plan, including a health benefits plan under the Federal Employees Health Benefit Plan under chapter 89 of title 5, United States Code, and a qualified retiree prescription drug plan (as defined by the Secretary), but only if (subject to subparagraph (E)(ii)) the coverage provides benefits at least equivalent to the benefits under a prescription drug card plan under this part.

"(D) Prescription drug coverage

UNDER CERTAIN MEDIGAP POLICIES.—Coverage

under a medicare supplemental policy under section 1882 that provides benefits for prescription drugs (whether or not such coverage conforms to the standards for packages of benefits under section 1882(p)(1)) and if (subject to subparagraph (E)(ii)) the coverage provides benefits at least equivalent to the benefits under a prescription drug card plan under this part.

- "(E) STATE PHARMACEUTICAL ASSIST-ANCE PROGRAM.—Coverage of prescription drugs under a State pharmaceutical assistance program, but only if (subject to subparagraph (E)(ii)) the coverage provides benefits at least equivalent to the benefits under a prescription drug card plan under this part.
- "(F) Veterans' coverage of prescription drugs for veterans under chapter 17 of title 38, United States Code, but only if (subject to subparagraph (E)(ii)) the coverage provides benefits at least equivalent to the benefits under a prescription drug card plan under this part.

For purposes of carrying out this paragraph, the certifications of the type described in sections 2701(e) of the Public Health Service Act and in sec-

- tion 9801(e) of the Internal Revenue Code of 1986
- 2 shall also include a statement for the period of cov-
- 3 erage of whether the individual involved had pre-
- 4 scription drug coverage described in this paragraph.
- 5 "(5) COMPETITION.—Each eligible entity with a
- 6 contract under this part shall compete for the enroll-
- 7 ment of beneficiaries in a prescription drug card
- 8 plan offered by the entity on the basis of discounts,
- 9 formularies, pharmacy networks, and other services
- 10 provided for under the contract.
- 11 "PROVIDING ENROLLMENT AND COVERAGE INFORMATION
- TO BENEFICIARIES
- "Sec. 1860C. (a) Activities.—The Secretary shall
- 14 provide for activities under this part to broadly dissemi-
- 15 nate information to eligible beneficiaries (and prospective
- 16 eligible beneficiaries) regarding enrollment under this part
- 17 and the prescription drug card plans offered by eligible
- 18 entities with a contract under this part.
- 19 "(b) Special Rule for First Enrollment
- 20 Under the Program.—To the extent practicable, the
- 21 activities described in subsection (a) shall ensure that eli-
- 22 gible beneficiaries are provided with such information at
- 23 least 60 days prior to the first enrollment period described
- 24 in section 1860B(c).

1	"ENROLLEE PROTECTIONS
2	"Sec. 1860D. (a) Requirements for All Eligi-
3	BLE ENTITIES.—Each eligible entity shall meet the fol-
4	lowing requirements:
5	"(1) Guaranteed issuance and non-
6	DISCRIMINATION.—
7	"(A) GUARANTEED ISSUANCE.—
8	"(i) In general.—An eligible bene-
9	ficiary who is eligible to enroll in a pre-
10	scription drug card plan offered by an eli-
11	gible entity under section 1860B(b) for
12	prescription drug coverage under this part
13	at a time during which elections are ac-
14	cepted under this part with respect to the
15	coverage shall not be denied enrollment
16	based on any health status-related factor
17	(described in section 2702(a)(1) of the
18	Public Health Service Act) or any other
19	factor.
20	"(ii) Medicare+choice limita-
21	TIONS PERMITTED.—The provisions of
22	paragraphs (2) and (3) (other than sub-
23	paragraph (C)(i), relating to default enroll-
24	ment) of section 1851(g) (relating to pri-
25	ority and limitation on termination of elec-

1	tion) shall apply to eligible entities under
2	this subsection.
3	"(B) Nondiscrimination.—An eligible
4	entity offering prescription drug coverage under
5	this part shall not establish a service area in a
6	manner that would discriminate based on health
7	or economic status of potential enrollees.
8	"(2) Disclosure of Information.—
9	"(A) Information.—
10	"(i) GENERAL INFORMATION.—Each
11	eligible entity with a contract under this
12	part to provide a prescription drug card
13	plan shall disclose, in a clear, accurate,
14	and standardized form to each eligible ben-
15	eficiary enrolled in a prescription drug dis-
16	count card program offered by such entity
17	under this part at the time of enrollment
18	and at least annually thereafter, the infor-
19	mation described in section 1852(c)(1) re-
20	lating to such prescription drug coverage.
21	"(ii) Specific information.—In ad-
22	dition to the information described in
23	clause (i), each eligible entity with a con-
24	tract under this part shall disclose the fol-
25	lowing:

1	"(I) How enrollees will have ac-
2	cess to covered outpatient drugs, in-
3	cluding access to such drugs through
4	pharmacy networks.
5	"(II) How any formulary used by
6	the eligible entity functions.
7	"(III) Information on grievance
8	and appeals procedures.
9	"(IV) Information on enrollment
10	fees and prices charged to the enrollee
11	for covered outpatient drugs.
12	"(V) Any other information that
13	the Secretary determines is necessary
14	to promote informed choices by eligi-
15	ble beneficiaries among eligible enti-
16	ties.
17	"(B) DISCLOSURE UPON REQUEST OF
18	GENERAL COVERAGE, UTILIZATION, AND GRIEV-
19	ANCE INFORMATION.—Upon request of an eligi-
20	ble beneficiary, the eligible entity shall provide
21	the information described in paragraph (3) to
22	such beneficiary.
23	"(C) Response to Beneficiary Ques-
24	TIONS.—Each eligible entity offering a prescrip-
25	tion drug discount card plan under this part

shall have a mechanism for providing specific information to enrollees upon request. The entity shall make available, through an Internet website and, upon request, in writing, information on specific changes in its formulary.

"(3) Grievance mechanism, coverage determinations, and reconsiderations.—

"(A) IN GENERAL.—With respect to the benefit under this part, each eligible entity offering a prescription drug discount card plan shall provide meaningful procedures for hearing and resolving grievances between the organization (including any entity or individual through which the eligible entity provides covered benefits) and enrollees with prescription drug card plans of the eligible entity under this part in accordance with section 1852(f).

"(B) APPLICATION OF COVERAGE DETER-MINATION AND RECONSIDERATION PROVI-SIONS.—Each eligible entity shall meet the requirements of paragraphs (1) through (3) of section 1852(g) with respect to covered benefits under the prescription drug card plan it offers under this part in the same manner as such requirements apply to a Medicare+Choice organi-

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zation with respect to benefits it offers under a Medicare+Choice plan under part C.

"(C) REQUEST FOR REVIEW OF TIERED FORMULARY DETERMINATIONS.—In the case of a prescription drug card plan offered by an eligible entity that provides for tiered cost-sharing for drugs included within a formulary and provides lower cost-sharing for preferred drugs included within the formulary, an individual who is enrolled in the plan may request coverage of a nonpreferred drug under the terms applicable for preferred drugs if the prescribing physician determines that the preferred drug for treatment of the same condition is not as effective for the individual or has adverse effects for the individual.

"(4) APPEALS.—

"(A) IN GENERAL.—Subject to subparagraph (B), each eligible entity offering a prescription drug card plan shall meet the requirements of paragraphs (4) and (5) of section 1852(g) with respect to drugs not included on any formulary in the same manner as such requirements apply to a Medicare+Choice organi-

1 zation with respect to benefits it offers under a 2 Medicare+Choice plan under part C. "(B) FORMULARY DETERMINATIONS.—An 3 4 individual who is enrolled in a prescription drug card plan offered by an eligible entity may ap-5 6 peal to obtain coverage under this part for a 7 covered outpatient drug that is not on a for-8 mulary of the eligible entity if the prescribing 9 physician determines that the formulary drug 10 for treatment of the same condition is not as 11 effective for the individual or has adverse ef-12 fects for the individual. 13 "(5) Confidentiality and accuracy of en-14 ROLLEE RECORDS.—Each eligible entity offering a 15 prescription drug discount card plan shall meet the 16 requirements of the Health Insurance Portability 17 and Accountability Act of 1996. 18 (b) Eligible Entities Offering a Discount 19 CARD PROGRAM.—If an eligible entity offers a discount 20 card program under this part, in addition to the require-21 ments under subsection (a), the entity shall meet the fol-22 lowing requirements: "(1) Access to covered benefits.— 23 "(A) Assuring Pharmacy access.— 24

1	"(i) In general.—The eligible entity
2	offering the prescription drug discount
3	card plan shall secure the participation in
4	its network of a sufficient number of phar-
5	macies that dispense (other than by mail
6	order) drugs directly to patients to ensure
7	convenient access (as determined by the
8	Secretary and including adequate emer-
9	gency access) for enrolled beneficiaries, in
10	accordance with standards established
11	under section 1860D(a)(3) that ensure
12	such convenient access.
13	"(ii) Use of point-of-service sys-
14	TEM.—Each eligible entity offering a pre-
15	scription drug discount card plan shall es-
16	tablish an optional point-of-service method
17	of operation under which—
18	"(I) the plan provides access to
19	any or all pharmacies that are not
20	participating pharmacies in its net-
21	work; and
22	"(II) discounts under the plan
23	may not be available.

1	The additional copayments so charged
2	shall not be counted as out-of-pocket ex-
3	penses for purposes of section 1860F(b).
4	"(B) USE OF STANDARDIZED TECH-
5	NOLOGY.—
6	"(i) In general.—Each eligible enti-
7	ty offering a prescription drug discount
8	card plan shall issue (and reissue, as ap-
9	propriate) such a card (or other tech-
10	nology) that may be used by an enrolled
11	beneficiary to assure access to negotiated
12	prices under section 1860F(a) for the pur-
13	chase of prescription drugs for which cov-
14	erage is not otherwise provided under the
15	prescription drug discount card plan.
16	"(ii) Standards.—The Secretary
17	shall provide for the development of na-
18	tional standards relating to a standardized
19	format for the card or other technology re-
20	ferred to in subparagraph (A). Such stand-
21	ards shall be compatible with standards es-
22	tablished under part C of title XI.
23	"(C) REQUIREMENTS ON DEVELOPMENT
24	AND APPLICATION OF FORMULARIES.—If an eli-
25	gible entity that offers a prescription drug dis-

count card plan uses a formulary, the following requirements must be met:

"(i) Pharmacy and therapeutic (P&T) COMMITTEE.—The eligible entity must establish a pharmacy and therapeutic committee that develops and reviews the formulary. Such committee shall include at least 1 physician and at least 1 pharmacist both with expertise in the care of elderly or disabled persons and a majority of its members shall consist of individuals who are a physician or a practicing pharmacist (or both).

"(ii) FORMULARY DEVELOPMENT.—In developing and reviewing the formulary, the committee shall base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, such as randomized clinical trials, pharmacoeconomic studies, outcomes research data, and such other information as the committee determines to be appropriate.

1	"(iii) Inclusion of drugs in all
2	THERAPEUTIC CATEGORIES.—The for-
3	mulary must include drugs within each
4	therapeutic category and class of covered
5	outpatient drugs (although not necessarily
6	for all drugs within such categories and
7	classes).
8	"(iv) Provider Education.—The
9	committee shall establish policies and pro-
10	cedures to educate and inform health care
11	providers concerning the formulary.
12	"(v) Notice before removing
13	DRUGS FROM FORMULARY.—Any removal
14	of a drug from a formulary shall take ef-
15	fect only after appropriate notice is made
16	available to beneficiaries and physicians.
17	"(vi) Grievances and appeals re-
18	LATING TO APPLICATION OF
19	FORMULARIES.—For provisions relating to
20	grievances and appeals of coverage, see
21	subsections (e) and (f).
22	"(2) Cost and utilization management;
23	QUALITY ASSURANCE; MEDICATION THERAPY MAN-
24	AGEMENT PROGRAM.—

1	"(A) IN GENERAL.—Each eligible entity
2	offering a prescription drug discount card plan
3	may have in place with respect to covered out-
4	patient drugs—
5	"(i) an effective cost and drug utiliza-
6	tion management program, including medi-
7	cally appropriate incentives to use generic
8	drugs and therapeutic interchange, when
9	appropriate;
10	"(ii) quality assurance measures and
11	systems to reduce medical errors and ad-
12	verse drug interactions, including a medi-
13	cation therapy management program de-
14	scribed in subparagraph (B) and an elec-
15	tronic prescription program described in
16	subparagraph (C); and
17	"(iii) a program to control fraud,
18	abuse, and waste.
19	Nothing in this section shall be construed as
20	impairing an eligible entity from applying cost
21	management tools (including differential pay-
22	ments) under all methods of operation.
23	"(B) Medication therapy management
24	PROGRAM —

1	"(i) In General.—A medication
2	therapy management program described in
3	this paragraph is a program of drug ther-
4	apy management and medication adminis-
5	tration that is designed to ensure, with re-
6	spect to beneficiaries with chronic diseases
7	(such as diabetes, asthma, hypertension,
8	and congestive heart failure) or multiple
9	prescriptions, that covered outpatient
10	drugs under the prescription drug discount
11	card plan are appropriately used to achieve
12	therapeutic goals and reduce the risk of
13	adverse events, including adverse drug
14	interactions.
15	"(ii) Elements.—Such program may
16	include—
17	"(I) enhanced beneficiary under-
18	standing of such appropriate use
19	through beneficiary education, coun-
20	seling, and other appropriate means;
21	"(II) increased beneficiary adher-
22	ence with prescription medication
23	regimens through medication refill re-
24	minders, special packaging, and other
25	appropriate means; and

1	"(III) detection of patterns of
2	overuse and underuse of prescription
3	drugs.
4	"(iii) Development of program in
5	COOPERATION WITH LICENSED PHAR-
6	MACISTS.—The program shall be developed
7	in cooperation with licensed pharmacists
8	and physicians.
9	"(iv) Considerations in Pharmacy
10	FEES.—Each eligible entity offering a pre-
11	scription drug discount card plan shall
12	take into account, in establishing fees for
13	pharmacists and others providing services
14	under the medication therapy management
15	program, the resources and time used in
16	implementing the program.
17	"(C) Treatment of accreditation.—
18	Section 1852(e)(4) (relating to treatment of ac-
19	creditation) shall apply to prescription drug dis-
20	count card plans under this part with respect to
21	the following requirements, in the same manner
22	as they apply to Medicare+Choice plans under
23	part C with respect to the requirements de-
24	scribed in a clause of section 1852(e)(4)(B):

1	"(i) Paragraph (1) (including quality
2	assurance), including any medication ther-
3	apy management program under para-
4	graph (2).
5	"(ii) Subsection (c)(1) (relating to ac-
6	cess to covered benefits).
7	"(iii) Subsection (g) (relating to con-
8	fidentiality and accuracy of enrollee
9	records).
10	"(D) Public disclosure of pharma-
11	CEUTICAL PRICES FOR EQUIVALENT DRUGS.—
12	Each eligible entity offering a prescription drug
13	discount card plan shall provide that each phar-
14	macy or other dispenser that arranges for the
15	dispensing of a covered outpatient drug shall
16	inform the beneficiary at the time of purchase
17	of the drug of any differential between the price
18	of the prescribed drug to the enrollee and the
19	price of the lowest cost generic drug covered
20	under the plan that is therapeutically equivalent
21	and bioequivalent.
22	"ANNUAL ENROLLMENT FEE
23	"Sec. 1860E. (a) Amount.—
24	"(1) In general.—Except as provided in sub-
25	section (c), enrollment under the program under this

1	part is conditioned upon payment of an annual en-
2	rollment fee of \$25.
3	"(2) Annual Percentage increase.—
4	"(A) IN GENERAL.—In the case of any cal-
5	endar year beginning after 2004, the dollar
6	amount in paragraph (1) shall be increased by
7	an amount equal to—
8	"(i) such dollar amount; multiplied by
9	"(ii) the inflation adjustment.
10	"(B) Inflation adjustment.—For pur-
11	poses of subparagraph (A)(ii), the inflation ad-
12	justment for any calendar year is the percent-
13	age (if any) by which—
14	"(i) the average per capita aggregate
15	expenditures for covered outpatient drugs
16	in the United States for medicare bene-
17	ficiaries, as determined by the Secretary
18	for the 12-month period ending in July of
19	the previous year; exceeds
20	"(ii) such aggregate expenditures for
21	the 12-month period ending with July
22	2003.
23	"(C) ROUNDING.—If any increase deter-
24	mined under clause (ii) is not a multiple of \$1,

1	such increase shall be rounded to the nearest
2	multiple of \$1.
3	"(b) Collection of Annual Enrollment Fee.—
4	"(1) In general.—Unless the eligible bene-
5	ficiary makes an election under paragraph (2), the
6	annual enrollment fee described in subsection (a)
7	shall be collected and credited to the Federal Sup-
8	plementary Medical Insurance Trust Fund in the
9	same manner as the monthly premium determined
10	under section 1839 is collected and credited to such
11	Trust Fund under section 1840.
12	"(2) DIRECT PAYMENT.—An eligible beneficiary
13	may elect to pay the annual enrollment fee directly
14	or in any other manner approved by the Secretary.
15	The Secretary shall establish procedures for making
16	such an election.
17	"(c) Waiver.—The Secretary shall waive the enroll-
18	ment fee described in subsection (a) in the case of an eligi-
19	ble beneficiary whose income is below 200 percent of the
20	poverty line.
21	"BENEFITS UNDER THE PROGRAM
22	"Sec. 1860F. (a) Access to Negotiated
23	Prices.—
24	"(1) Negotiated prices.—
25	"(A) In General.—Subject to subpara-
26	graph (B), each prescription drug card plan of-

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fering a discount card program by an eligible entity with a contract under this part shall provide each eligible beneficiary enrolled in such plan with access to negotiated prices (including discounts) for such prescription applicable drugs as the eligible entity determines appropriate. Such discounts may include discounts for nonformulary drugs. If such a beneficiary becomes eligible for the catastrophic benefit under subsection (b), the negotiated prices (including applicable discounts) shall continue to be available to the beneficiary for those prescription drugs for which payment may not be made under section 1860H(b). For purposes of this subparagraph, the term 'prescription drugs' is not limited to covered outpatient drugs, but does not include any over-the-counter drug that is not a covered outpatient drug.

"(B) Limitations.—

"(i) FORMULARY RESTRICTIONS.—Insofar as an eligible entity with a contract under this part uses a formulary, the negotiated prices (including applicable discounts) for nonformulary drugs may differ.

"(ii) Avoidance of duplicate cov-ERAGE.—The negotiated prices (including applicable discounts) for prescription drugs shall not be available for any drug prescribed for an eligible beneficiary if pay-ment for the drug is available under part A or B (but such negotiated prices shall be available if payment under part A or B is not available because the beneficiary has not met the deductible or has exhausted benefits under part A or B).

- "(2) DISCOUNT CARD.—The Secretary shall develop a uniform standard card format to be issued by each eligible entity offering a prescription drug discount card plan that shall be used by an enrolled beneficiary to ensure the access of such beneficiary to negotiated prices under paragraph (1).
- "(3) Ensuring discounts in all areas.—
 The Secretary shall develop procedures that ensure that each eligible beneficiary that resides in an area where no prescription drug discount card plans are available is provided with access to negotiated prices for prescription drugs (including applicable discounts).
- 25 "(b) Catastrophic Benefit.—

"(1) IN GENERAL.—Subject to paragraph (4) (relating to eligibility for the catastrophic benefit) and any formulary used by the prescription drug discount card program in which the eligible beneficiary is enrolled, the catastrophic benefit shall be administered as follows:

"(A) BENEFICIARIES WITH ANNUAL INCOMES BELOW 200 PERCENT OF THE POVERTY LINE.—In the case of an eligible beneficiary whose modified adjusted gross income (as defined in paragraph (4)(E)) is below 200 percent of the poverty line, the beneficiary shall not be responsible for making a payment for a covered outpatient drug provided under this part to the beneficiary in a year to the extent that the out-of-pocket expenses of the beneficiary for such drug exceed \$1,500, unless the Secretary implements cost-sharing (as authorized under this part).

"(B) BENEFICIARIES WITH ANNUAL IN-COMES BETWEEN 200 AND 400 PERCENT OF THE POVERTY LINE.—In the case of an eligible beneficiary whose modified adjusted gross income (as so defined) equals or exceeds 200 percent, but does not exceed 400 percent, of the poverty

line, the beneficiary shall not be responsible for making a payment for a covered outpatient drug provided under this part to the beneficiary in a year to the extent that the out-of-pocket expenses of the beneficiary for such drug exceed \$3,500, unless the Secretary implements cost-sharing (as authorized under this part).

"(C) Beneficiaries with annual incomes between 400 and 600 percent of the poverty line.—In the case of an eligible beneficiary whose modified adjusted gross income (as so defined) equals or exceeds 400 percent, but does not exceed 600 percent, of the poverty line, the beneficiary shall not be responsible for making a payment for a covered outpatient drug provided under this part to the beneficiary in a year to the extent that the out-of-pocket expenses of the beneficiary for such drug exceed \$5,500, unless the Secretary implements cost-sharing (as authorized under this part).

"(D) BENEFICIARIES WITH ANNUAL IN-COMES THAT EXCEED 600 PERCENT OF THE POVERTY LINE.—In the case of an eligible beneficiary whose modified adjusted gross income (as so defined) equals or exceeds 600 percent of

1 the poverty line, the beneficiary shall not be re-2 sponsible for making a payment for a covered outpatient drug provided under this part to the 3 4 beneficiary in a year to the extent that the out-5 of-pocket expenses of the beneficiary for such 6 drug exceeds 20 percent of that beneficiary's in-7 come, unless the Secretary implements cost-8 sharing (as authorized under this part). "(2) Annual Percentage increase.— 9 "(A) IN GENERAL.—In the case of any cal-10 11 endar year after 2004, the dollar amounts in 12 paragraph (1) shall be increased by an amount 13 equal to— 14 "(i) such dollar amount; multiplied by "(ii) the inflation adjustment deter-15 16 mined under section 1860E(a)(2)(B) for 17 such calendar year. 18 "(B) ROUNDING.—If any increase deter-19 mined under subparagraph (A) is not a multiple 20 of \$1, such increase shall be rounded to the 21 nearest multiple of \$1. 22 "(3) Eligible entity not at risk for cata-23 STROPHIC BENEFIT.— "(A) IN GENERAL.—The Secretary, and 24 25 not the eligible entity, shall be at risk for the

1	provision of the catastrophic benefit under this
2	subsection.
3	"(B) Provisions relating to payments
4	TO ELIGIBLE ENTITIES.—For provisions relat-
5	ing to payments to eligible entities for admin-
6	istering the catastrophic benefit under this sub-
7	section, see section 1860H.
8	"(C) Procedures for determining
9	MODIFIED ADJUSTED GROSS INCOME.—
10	"(i) In General.—The Secretary
11	shall establish procedures for determining
12	the modified adjusted gross income of eligi-
13	ble beneficiaries enrolled under this part.
14	"(ii) Consultation.—The Secretary
15	shall consult with the Secretary of the
16	Treasury in making the determinations de-
17	scribed in clause (i).
18	"(iii) Disclosure of Informa-
19	TION.—Notwithstanding section 6103(a) of
20	the Internal Revenue Code of 1986, the
21	Secretary of the Treasury may, upon writ-
22	ten request from the Secretary, disclose to
23	officers and employees of the Centers for
24	Medicare & Medicaid Services such return
25	information as is necessary to make the

1	determinations described in clause (i). Re-
2	turn information disclosed under the pre-
3	ceding sentence may be used by officers
4	and employees of the Centers for Medicare
5	& Medicaid Services only for the purposes
6	of, and to the extent necessary, in making
7	such determinations.
8	"(D) Definition of modified adjusted
9	GROSS INCOME.—In this paragraph, the term
10	'modified adjusted gross income' means ad-
11	justed gross income (as defined in section 62 of
12	the Internal Revenue Code of 1986)—
13	"(i) determined without regard to sec-
14	tions 135, 911, 931, and 933 of such
15	Code;
16	"(ii) increased by the amount of inter-
17	est received or accrued by the taxpayer
18	during the taxable year which is exempt
19	from tax under such Code; and
20	"(iii) increased by any amount re-
21	ceived under title II.
22	"(5) Ensuring catastrophic benefit in
23	ALL AREAS.—The Secretary shall develop procedures
24	for the provision of the catastrophic benefit under
25	this subsection to each eligible beneficiary that re-

1	sides in an area where there are no prescription
2	drug discount card plans offered that have been
3	awarded a contract under this part.
4	"REQUIREMENTS FOR ENTITIES TO PROVIDE
5	PRESCRIPTION DRUG COVERAGE
6	"Sec. 1860G. (a) Establishment of Bidding
7	Process.—The Secretary shall establish a process under
8	which the Secretary accepts bids from eligible entities and
9	awards contracts to the entities to provide the benefits
10	under this part to eligible beneficiaries in an area.
11	"(b) Submission of Bids.—Each eligible entity de-
12	siring to enter into a contract under this part shall submit
13	a bid to the Secretary at such time, in such manner, and
14	accompanied by such information as the Secretary may
15	require.
16	"(c) Administrative Fee Bid.—
17	"(1) Submission.—For the bid described in
18	subsection (b), each entity shall submit to the Sec-
19	retary information regarding administration of the
20	discount card and catastrophic benefit under this
21	part.
22	"(2) Bid submission requirements.—
23	"(A) Administrative fee bid submis-
24	SION.—In submitting bids, the entities shall in-
25	clude separate costs for administering the dis-
26	count card component, if applicable, and the

1	catastrophic benefit. The entity shall submit the
2	administrative fee bid in a form and manner
3	specified by the Secretary, and shall include a
4	statement of projected enrollment and a sepa-
5	rate statement of the projected administrative
6	costs for at least the following functions:
7	"(i) Enrollment, including income eli-
8	gibility determination.
9	"(ii) Claims processing.
10	"(iii) Quality assurance, including
11	drug utilization review.
12	"(iv) Beneficiary and pharmacy cus-
13	tomer service.
14	"(v) Coordination of benefits.
15	"(vi) Fraud and abuse prevention.
16	"(B) Negotiated administrative fee
17	BID AMOUNTS.—The Secretary has the author-
18	ity to negotiate regarding the bid amounts sub-
19	mitted. The Secretary may reject a bid if the
20	Secretary determines it is not supported by the
21	administrative cost information provided in the
22	bid as specified in subparagraph (A).
23	"(C) PAYMENT TO PLANS BASED ON AD-
24	MINISTRATIVE FEE BID AMOUNTS.—The Sec-
25	retary shall use the bid amounts to calculate a

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benchmark amount consisting of the enrollment-weighted average of all bids for each function and each class of entity. The class of entity is either a regional or national entity, or such other classes as the Secretary may determine to be appropriate. The functions are the discount card and catastrophic components. If an eligible entity's combined bid for both functions is above the combined benchmark within the entity's class for the functions, the eligible entity collect additional necessary shall revenue through one or both of the following:

- "(i) Additional fees charged to the beneficiary, not to exceed \$25 annually.
- "(ii) Use of rebate amounts from drug manufacturers to defray administrative costs.

"(d) Awarding of Contracts.—

"(1) IN GENERAL.—The Secretary shall, consistent with the requirements of this part and the goal of containing medicare program costs, award at least 2 contracts in each area, unless only 1 bidding entity meets the terms and conditions specified by the Secretary under paragraph (2).

- "(2) TERMS AND CONDITIONS.—The Secretary shall not award a contract to an eligible entity under this section unless the Secretary finds that the eligible entity is in compliance with such terms and conditions as the Secretary shall specify.
 - "(3) REQUIREMENTS FOR ELIGIBLE ENTITIES
 PROVIDING DISCOUNT CARD PROGRAM.—Except as
 provided in subsection (e), in determining which of
 the eligible entities that submitted bids that meet
 the terms and conditions specified by the Secretary
 under paragraph (2) to award a contract, the Secretary shall consider whether the bid submitted by
 the entity meets at least the following requirements:
 - "(A) Level of savings to medicare beneficiaries who enroll in the program discounts on prescription drugs, including discounts negotiated with manufacturers.
 - "(B) Prohibition on application only to mail order and provides convenient access to retail pharmacies.
- "(C) Level of Beneficiary Services.—

 The program provides pharmaceutical support

services, such as education and services to prevent adverse drug interactions.

- "(D) ADEQUACY OF INFORMATION.—The program makes available to medicare beneficiaries through the Internet and otherwise information, including information on enrollment fees, prices charged to beneficiaries, and services offered under the program, that the Secretary identifies as being necessary to provide for informed choice by beneficiaries among endorsed programs.
- "(E) EXTENT OF DEMONSTRATED EXPERI-ENCE.—The entity operating the program has demonstrated experience and expertise in operating such a program or a similar program.
- "(F) EXTENT OF QUALITY ASSURANCE.—
 The entity has in place adequate procedures for assuring quality service under the program.
- "(G) OPERATION OF ASSISTANCE PRO-GRAM.—The entity meets such requirements relating to solvency, compliance with financial reporting requirements, audit compliance, and contractual guarantees as specified by the Secretary.

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"(H) Privacy compliance.—The entity implements policies and procedures to safeguard the use and disclosure of program beneficiaries' individually identifiable health information in a manner consistent with the Federal regulations (concerning the privacy of individually identifiable health information) promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

"(I) Additional Beneficiary Protections.—The program meets such additional requirements as the Secretary identifies to protect and promote the interest of medicare beneficiaries, including requirements that ensure that beneficiaries are not charged more than the lower of the negotiated retail price or the usual and customary price.

The prices negotiated by a prescription drug discount card program endorsed under this section shall (notwithstanding any other provision of law) not be taken into account for the purposes of establishing the best price under section 1927(c)(1)(C).

"(4) Beneficiary access to savings and repairs.—The Secretary shall require eligible enti-

- ties offering a discount card program to pass on savings and rebates negotiated with manufacturers to eligible beneficiaries enrolled with the entity.
- "(5) Negotiated agreements with 5 PLOYER-SPONSORED PLANS.—Notwithstanding any other provision of this part, the Secretary may nego-6 7 tiate agreements with employer-sponsored plans 8 under which eligible beneficiaries are provided with 9 a benefit for prescription drug coverage that is more 10 generous than the benefit that would otherwise have 11 been available under this part if such an agreement 12 results in cost savings to the Federal Government.
- "(e) REQUIREMENTS FOR OTHER ELIGIBLE ENTI-14 TIES.—If an eligible entity is licensed under State law to 15 provide the benefit under this section, such entity shall 16 not be required to meet the requirements of subsection 17 (d)(3). If an eligible entity offers a national plan, such 18 entity shall not be required to meet the requirements of 19 subsection (d)(3), but shall meet the requirements of Em-
- 20 ployee Retirement Income Security Act of 1974 that apply
- 21 with respect to such plan.
- 22 "PAYMENTS TO ELIGIBLE ENTITIES FOR ADMINISTERING
- 23 THE CATASTROPHIC BENEFIT
- "Sec. 1860H. (a) IN GENERAL.—The Secretary may
- 25 establish procedures for making payments to an eligible
- 26 entity under a contract entered into under this part for—

1	"(1) no less than 90 percent of the costs of pro-
2	viding covered outpatient prescription drugs to bene-
3	ficiaries eligible for the benefit under this part in ac-
4	cordance with subsection (b); and
5	"(2) costs incurred by the entity in admin-
6	istering the catastrophic benefit in accordance with
7	section 1860G.
8	"(b) Payment for Covered Outpatient Pre-
9	SCRIPTION DRUGS.—
10	"(1) In general.—Except as provided in sub-
11	section (c) and subject to paragraph (2), the Sec-
12	retary may only pay an eligible entity for covered
13	outpatient drugs furnished by the eligible entity to
14	an eligible beneficiary enrolled with such entity
15	under this part that is eligible for the catastrophic
16	benefit under section 1860F(b).
17	"(2) Limitations.—
18	"(A) FORMULARY RESTRICTIONS.—Insofar
19	as an eligible entity with a contract under this
20	part uses a formulary, the Secretary may not
21	make any payment for a covered outpatient
22	drug that is not included in such formulary, ex-
23	cept to the extent provided under section

1860D(a)(4)(B).

"(B) 1 NEGOTIATED PRICES.—The Sec-2 retary may not pay an amount for a covered 3 outpatient drug furnished to an eligible bene-4 ficiary that exceeds the negotiated price (includ-5 ing applicable discounts) that the beneficiary 6 would have been responsible for under section 7 1860F(a) or the price negotiated for insurance 8 coverage under the Medicare+Choice program 9 under part C, a medicare supplemental policy, 10 employer-sponsored coverage, or a State plan.

"(C) Cost-sharing limitations.—An eligible entity may not charge an individual enrolled with such entity who is eligible for the catastrophic benefit under this part any copayment, tiered copayment, coinsurance, or other cost-sharing that exceeds 10 percent of the cost of the drug that is dispensed to the individual.

"(3) Payment in competitive areas.—In a geographic area in which 2 or more eligible entities offer a plan under this part, the Secretary may negotiate an agreement with the entity to reimburse the entity for costs incurred in providing the benefit under this part on a capitated basis.

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1	"(c) Secondary Payer Provisions.—The provi-
2	sions of section 1862(b) shall apply to the benefits pro-
3	vided under this part.
4	"DETERMINATION OF INCOME LEVELS
5	"Sec. 1860I. (a) Determination of Income Lev-
6	ELS.—
7	"(1) IN GENERAL.—The Secretary, in consulta-
8	tion with the Secretary of the Treasury, shall estab-
9	lish procedures under which each eligible entity
10	awarded a contract under this part determines the
11	income levels of eligible beneficiaries enrolled in a
12	prescription drug card plan offered by that entity at
13	least annually for purposes of sections 1860E(c) and
14	1860F(b).
15	"(2) Procedures.—
16	"(A) In general.—Except as provided in
17	subparagraph (B), the procedures established
18	under paragraph (1) shall—
19	"(i) require each eligible beneficiary
20	who is enrolled in a prescription drug card
21	plan to present the Federal income tax re-
22	turn for the preceding taxable year to the
23	eligible entity offering the plan as proof of
24	income for that year;
25	"(ii) require, upon the request of an
26	eligible entity, the Secretary of the Treas-

1	ury to confirm the amount of income re-
2	ported on such a Federal income tax re-
3	turn; and
4	"(iii) attribute, in the case of a joint
5	return, ½ of the income reported on the
6	return to each eligible beneficiary filing
7	such a return.
8	"(B) OTHER PROOF OF INCOME.—If an eligible
9	beneficiary did not file a Federal income tax return
10	for the preceding year, if such beneficiary experi-
11	ences a significant decrease in income during a year
12	or if such other circumstances exist as the Secretary
13	may specify, an eligible beneficiary may submit an
14	affidavit and such supporting documents as the Sec-
15	retary may require as proof of the income of that
16	beneficiary instead of a Federal income tax return
17	"(b) Enforcement of Income Determina-
18	TIONS.—The Secretary, in consultation with the Secretary
19	of the Treasury, shall—
20	"(1) establish procedures that ensure that eligi-
21	ble beneficiaries comply with sections 1860E(c) and
22	1860F(b); and
23	"(2) require, if the Secretary determines that
24	nayments were made under this part to which an eli-

gible beneficiary was not entitled, the repayment of any excess payments with interest and a penalty.

"(c) QUALITY CONTROL SYSTEM.—

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- "(1) ESTABLISHMENT.—The Secretary shall establish a quality control system to monitor income determinations made by eligible entities under this section and to produce appropriate and comprehensive measures of error rates.
- 9 "(2) PERIODIC AUDITS.—The Inspector General 10 of the Department of Health and Human Services 11 shall conduct periodic audits to ensure that the sys-12 tem established under paragraph (1) is functioning 13 appropriately.

14 "APPROPRIATIONS

"Sec. 1860J. There are authorized to be appropriated from time to time, out of any moneys in the Treasury not otherwise appropriated, to the Federal Supplementary Medical Insurance Trust Fund established under section 1841, an amount equal to the amount by which the benefits and administrative costs of providing the benefits under this part exceed the enrollment fees collected under section 1860E.

1	"MEDICARE COMPETITION AND PRESCRIPTION DRUG
2	ADVISORY BOARD
3	"Sec. 1860K. (a) Establishment of Board.—
4	There is established a Medicare Prescription Drug Advi-
5	sory Board (in this section referred to as the 'Board').
6	"(b) Advice on Policies; Reports.—
7	"(1) Advice on policies.—The Board shall
8	advise the Secretary on policies relating to the Medi-
9	care Outpatient Prescription Drug Discount and Se-
10	curity Program under this part.
11	"(2) Reports.—
12	"(A) IN GENERAL.—With respect to mat-
13	ters of the administration of the program under
14	this part, the Board shall submit to Congress
15	and to the Secretary such reports as the Board
16	determines appropriate. Each such report may
17	contain such recommendations as the Board de-
18	termines appropriate for legislative or adminis-
19	trative changes to improve the administration of
20	the program under this part. Each such report
21	shall be published in the Federal Register.
22	"(B) Maintaining independence of
23	BOARD.—The Board shall directly submit to
24	Congress reports required under subparagraph
25	(A). No officer or agency of the United States

1	may require the Board to submit to any officer
2	or agency of the United States for approval,
3	comments, or review, prior to the submission to
4	Congress of such reports.
5	"(c) STRUCTURE AND MEMBERSHIP OF THE
6	Board.—
7	"(1) Membership.—The Board shall be com-
8	posed of 7 members who shall be appointed as fol-
9	lows:
10	"(A) Presidential appointments.—
11	"(i) IN GENERAL.—Three members
12	shall be appointed by the President, by and
13	with the advice and consent of the Senate.
14	"(ii) Limitation.—Not more than 2
15	such members may be from the same polit-
16	ical party.
17	"(B) Senatorial appointments.—Two
18	members (each member from a different polit-
19	ical party) shall be appointed by the President
20	pro tempore of the Senate with the advice of
21	the Chairman and the Ranking Minority Mem-
22	ber of the Committee on Finance of the Senate.
23	"(C) Congressional appointments.—
24	Two members (each member from a different
25	political party) shall be appointed by the Speak-

1	er of the House of Representatives, with the ad-
2	vice of the Chairman and the Ranking Minority
3	Member of the Committee on Ways and Means
4	of the House of Representatives.
5	"(2) QUALIFICATIONS.—The members shall be
6	chosen on the basis of their integrity, impartiality,
7	and good judgment, and shall be individuals who
8	are, by reason of their education, experience, and at-
9	tainments, exceptionally qualified to perform the du-
10	ties of members of the Board.
11	"(3) Composition.—Of the members appointed
12	under paragraph (1)—
13	"(A) at least one shall represent the phar-
14	maceutical industry;
15	"(B) at least one shall represent physi-
16	cians;
17	"(C) at least one shall represent medicare
18	beneficiaries;
19	"(D) at least one shall represent practicing
20	pharmacists; and
21	"(E) at least one shall represent eligible
22	entities.
23	"(d) Terms of Appointment.—

1	"(1) In general.—Subject to paragraph (2),
2	each member of the Board shall serve for a term of
3	6 years.
4	"(2) Continuance in office and staggered
5	TERMS.—
6	"(A) CONTINUANCE IN OFFICE.—A mem-
7	ber appointed to a term of office after the com-
8	mencement of such term may serve under such
9	appointment only for the remainder of such
10	term.
11	"(B) Staggered terms.—The terms of
12	service of the members initially appointed under
13	this section shall begin on January 1, 2004,
14	and expire as follows:
15	"(i) Presidential appointments.—
16	The terms of service of the members ini-
17	tially appointed by the President shall ex-
18	pire as designated by the President at the
19	time of nomination, 1 each at the end of—
20	"(I) 2 years;
21	"(II) 4 years; and
22	"(III) 6 years.
23	"(ii) Senatorial appointments.—
24	The terms of service of members initially
25	appointed by the President pro tempore of

1	the Senate shall expire as designated by
2	the President pro tempore of the Senate at
3	the time of nomination, 1 each at the end
4	of—
5	"(I) 3 years; and
6	"(II) 6 years.
7	"(iii) Congressional appoint-
8	MENTS.—The terms of service of members
9	initially appointed by the Speaker of the
10	House of Representatives shall expire as
11	designated by the Speaker of the House of
12	Representatives at the time of nomination,
13	1 each at the end of—
14	"(I) 4 years; and
15	" (II) 5 years.
16	"(C) Reappointments.—Any person ap-
17	pointed as a member of the Board may not
18	serve for more than 8 years.
19	"(D) Vacancies.—Any member appointed
20	to fill a vacancy occurring before the expiration
21	of the term for which the member's predecessor
22	was appointed shall be appointed only for the
23	remainder of that term. A member may serve
24	after the expiration of that member's term until
25	a successor has taken office. A vacancy in the

- Board shall be filled in the manner in which the original appointment was made.

 ''(e) Chairperson.—A member of the Board shall
- 4 be designated by the President to serve as Chairperson
- 5 for a term of 4 years, coincident with the term of the
- 6 President, or until the designation of a successor.
- 7 "(f) Expenses and Per Diem.—Members of the
- 8 Board shall serve without compensation, except that, while
- 9 serving on business of the Board away from their homes
- 10 or regular places of business, members may be allowed
- 11 travel expenses, including per diem in lieu of subsistence,
- 12 as authorized by section 5703 of title 5, United States
- 13 Code, for persons in the Government employed intermit-
- 14 tently.
- 15 "(g) MEETING.—
- 16 "(1) IN GENERAL.—The Board shall meet at
- the call of the Chairperson (in consultation with the
- other members of the Board) not less than 4 times
- each year to consider a specific agenda of issues, as
- determined by the Chairperson in consultation with
- 21 the other members of the Board.
- 22 "(2) Quorum.—Four members of the Board
- (not more than 3 of whom may be of the same polit-
- ical party) shall constitute a quorum for purposes of
- conducting business.

1	"(h) Federal Advisory Committee Act.—The
2	Board shall be exempt from the provisions of the Federal
3	Advisory Committee Act (5 U.S.C. App.).
4	"(i) Personnel.—
5	"(1) STAFF DIRECTOR.—The Board shall, with-
6	out regard to the provisions of title 5, United States
7	Code, relating to the competitive service, appoint a
8	Staff Director who shall be paid at a rate equivalent
9	to a rate established for the Senior Executive Serv-
10	ice under section 5382 of title 5, United States
11	Code.
12	"(2) Staff.—
13	"(A) IN GENERAL.—The Board may em-
14	ploy, without regard to chapter 31 of title 5,
15	United States Code, such officers and employ-
16	ees as are necessary to administer the activities
17	to be carried out by the Board.
18	"(B) Flexibility with respect to
19	CIVIL SERVICE LAWS.—
20	"(i) In general.—The staff of the
21	Board shall be appointed without regard to
22	the provisions of title 5, United States
23	Code, governing appointments in the com-
24	petitive service, and, subject to clause (ii),
25	shall be paid without regard to the provi-

- 1 sions of chapters 51 and 53 of such title 2 (relating to classification and schedule pay 3 rates). MAXIMUM RATE.—In no case may the rate of compensation determined 6 under clause (i) exceed the rate of basic 7 pay payable for level IV of the Executive 8 Schedule under section 5315 of title 5, 9 United States Code. 10 "(j) Authorization of Appropriations.—There are authorized to be appropriated, out of the Federal Sup-11 12 plemental Medical Insurance Trust Fund established under section 1841, and the general fund of the Treasury, such sums as are necessary to carry out the purposes of 14 15 this section.". 16 (b) Conforming References to Previous Part D.— 17 18 (1) IN GENERAL.—Any reference in law (in ef-19 fect before the date of enactment of this Act) to part 20 D of title XVIII of the Social Security Act is deemed 21 a reference to part E of such title (as in effect after 22 such date). 23 (2) Secretarial submission of Legislative 24 PROPOSAL.—Not later than 6 months after the date
- of enactment of this section, the Secretary of Health

and Human Services shall submit to the appropriate committees of Congress a legislative proposal providing for such technical and conforming amendments in the law as are required by the provisions of this section.

(c) Effective Date.—

- (1) IN GENERAL.—The amendment made by subsection (a) shall take effect on the date of enactment of this Act.
- (2) IMPLEMENTATION.—Notwithstanding any provision of part D of title XVIII of the Social Security Act (as added by subsection (a)), the Secretary of Health and Human Services shall implement the Voluntary Medicare Outpatient Prescription Drug Discount and Security Program established under such part in a manner such that—
 - (A) benefits under such part for eligible beneficiaries (as defined in section 1860 of such Act, as added by such subsection) with annual incomes below 200 percent of the poverty line (as defined in such section) are available to such beneficiaries not later than the date that is 6 months after the date of enactment of this Act; and

1	(B) benefits under such part for other eli-
2	gible beneficiaries are available to such bene-
3	ficiaries not later than the date that is 1 year
4	after the date of enactment of this Act.
5	SEC. 3. ADMINISTRATION OF VOLUNTARY MEDICARE OUT-
6	PATIENT PRESCRIPTION DRUG DISCOUNT
7	AND SECURITY PROGRAM.
8	(a) Establishment of Center for Medicare
9	PRESCRIPTION DRUGS.—There is established, within the
10	Centers for Medicare & Medicaid Services of the Depart-
11	ment of Health and Human Services, a Center for Medi-
12	care Prescription Drugs. Such Center shall be separate
13	from the Center for Beneficiary Choices, the Center for
14	Medicare Management, and the Center for Medicaid and
15	State Operations.
16	(b) Duties.—It shall be the duty of the Center for
17	Medicare Prescription Drugs to administer the Voluntary
18	Medicare Outpatient Prescription Drug Discount and Se-
19	curity Program established under part D of title XVIII
20	of the Social Security Act (as added by section 2).
21	(c) Director.—
22	(1) APPOINTMENT.—There shall be in the Cen-
23	ter for Medicare Prescription Drugs a Director of
24	Medicare Prescription Drugs, who shall be appointed

1	by the President, by and with the advice and consent
2	of the Senate.
3	(2) Responsibilities.—The Director shall be
4	responsible for the exercise of all powers and the dis-
5	charge of all duties of the Center for Medicare Pre-
6	scription Drugs and shall have authority and control
7	over all personnel and activities thereof.
8	(d) Personnel.—The Director of the Center for
9	Medicare Prescription Drugs may appoint and terminate
10	such personnel as may be necessary to enable the Center
11	for Medicare Prescription Drugs to perform its duties.
12	SEC. 4. EXCLUSION OF PART D COSTS FROM DETERMINA-
13	TION OF PART B MONTHLY PREMIUM.
14	Section 1839(g) of the Social Security Act (42 U.S.C.
15	1395r(g)) is amended—
16	(1) by striking "attributable to the application
17	of section" and inserting "attributable to—
18	"(1) the application of section";
19	(2) by striking the period and inserting ";
20	and"; and
21	(3) by adding at the end the following new
22	paragraph:
23	"(2) the Voluntary Medicare Outpatient Pre-
24	scription Drug Discount and Security Program

1 SEC. 5. MEDIGAP REVISIONS.

2	Section 1882 of the Social Security Act (42 U.S.C.
3	1395ss) is amended by adding at the end the following
4	new subsection:
5	"(v) Modernization of Medicare Supplemental
6	Policies.—
7	"(1) Promulgation of model regula-
8	TION.—
9	"(A) NAIC MODEL REGULATION.—If,
10	within 9 months after the date of enactment of
11	the Medicare Rx Drug Discount and Security
12	Act of 2002, the National Association of Insur-
13	ance Commissioners (in this subsection referred
14	to as the 'NAIC') changes the 1991 NAIC
15	Model Regulation (described in subsection (p))
16	to revise the benefit package classified as 'J'
17	under the standards established by subsection
18	(p)(2) (including the benefit package classified
19	as 'J' with a high deductible feature, as de-
20	scribed in subsection (p)(11)) so that—
21	"(i) the coverage for outpatient pre-
22	scription drugs available under such ben-
23	efit package is replaced with coverage for
24	outpatient prescription drugs that com-
25	plements but does not duplicate the bene-
26	fits for outpatient prescription drugs that

1	beneficiaries are otherwise entitled to
2	under this title;
3	"(ii) a uniform format is used in the
4	policy with respect to such revised benefits;
5	and
6	"(iii) such revised standards meet any
7	additional requirements imposed by the
8	Medicare Rx Drug Discount and Security
9	Act of 2002;
10	subsection (g)(2)(A) shall be applied in each
11	State, effective for policies issued to policy hold-
12	ers on and after January 1, 2004, as if the ref-
13	erence to the Model Regulation adopted on
14	June 6, 1979, were a reference to the 1991
15	NAIC Model Regulation as changed under this
16	subparagraph (such changed regulation referred
17	to in this section as the '2004 NAIC Model
18	Regulation').
19	"(B) REGULATION BY THE SECRETARY.—
20	If the NAIC does not make the changes in the
21	1991 NAIC Model Regulation within the 9-
22	month period specified in subparagraph (A), the
23	Secretary shall promulgate, not later than 9
24	months after the end of such period, a regula-
25	tion and subsection (g)(2)(A) shall be applied in

each State, effective for policies issued to policy holders on and after January 1, 2004, as if the reference to the Model Regulation adopted on June 6, 1979, were a reference to the 1991 NAIC Model Regulation as changed by the Secretary under this subparagraph (such changed regulation referred to in this section as the '2004 Federal Regulation').

- "(C) Consultation with working GROUP.—In promulgating standards under this paragraph, the NAIC or Secretary shall consult with a working group similar to the working group described in subsection (p)(1)(D).
- "(D) Modification of Standards IF Medicare Benefits Change.—If benefits under part D of this title are changed and the Secretary determines, in consultation with the NAIC, that changes in the 2004 NAIC Model Regulation or 2004 Federal Regulation are needed to reflect such changes, the preceding provisions of this paragraph shall apply to the modification of standards previously established in the same manner as they applied to the original establishment of such standards.

1	"(2) Construction of Benefits in other
2	MEDICARE SUPPLEMENTAL POLICIES.—Nothing in
3	the benefit packages classified as 'A' through 'I'
4	under the standards established by subsection (p)(2)
5	(including the benefit package classified as 'F' with
6	a high deductible feature, as described in subsection
7	(p)(11)) shall be construed as providing coverage for
8	benefits for which payment may be made under part
9	D.
10	"(3) Application of provisions and con-
11	FORMING REFERENCES.—
12	"(A) APPLICATION OF PROVISIONS.—The
13	provisions of paragraphs (4) through (10) of
14	subsection (p) shall apply under this section,
15	except that—
16	"(i) any reference to the model regu-
17	lation applicable under that subsection
18	shall be deemed to be a reference to the
19	applicable 2004 NAIC Model Regulation or
20	2004 Federal Regulation; and
21	"(ii) any reference to a date under
22	such paragraphs of subsection (p) shall be
23	deemed to be a reference to the appro-
24	priate date under this subsection.

1 "(B) OTHER REFERENCES.—Any reference 2 to a provision of subsection (p) or a date appli-3 cable under such subsection shall also be con-4 sidered to be a reference to the appropriate pro-5 vision or date under this subsection.".

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